

19. (Original) The formulation of claim 16, wherein the formulation is in the form of a hard gelatin capsule or a soft gelatin capsule.

20. (Cancelled)

Sub 1
21. (Currently amended) The formulation of claim 16, wherein the [formulation comprises] the homocysteine-lowering agent is present in an amount of at least 200 µg [of the at least one homocysteine-lowering agent].

22. (Currently amended) The formulation of claim 16, wherein the [formulation comprises] homocysteine-lowering agent is 5 mg of vitamin B12.

23. (Original) The formulation of claim 16, wherein the at least one EFA is a eicosapentaenoic acid (EPA).

24. (Original) The formulation of claim 23, wherein the eicosapentaenoic acid (EPA) is the ethyl ester form or the pure tri-EPA triglyceride form.

25. (Original) The formulation of claim 16, wherein the EFA is arachidonic acid.

26. (Original) The formulation of claim 16, wherein the EFA is gammalinolenic acid or dihomogammalinolenic acid.

27. (Original) The formulation of claim 16, wherein the EFA is docosahexaenoic acid.

28. (Currently amended) The formulation of claim 16, wherein [the formulation comprises] two or more EFAs are present.

29. (Currently amended) The formulation of claim 16, wherein the [formulation comprises] EFA is at least 5% of the [at least one EFA] formulation.

64
30. (Currently amended) The formulation of claim 16, wherein the [formulation comprises] EFA is 15% or more of the [at least one EFA] formulation.

31. (Currently amended) The formulation of claim 16, wherein the [formulation comprises] EFA is 30% or more of the [at least one EFA] formulation.

32. (Currently amended) The formulation of claim 16, wherein the [formulation comprises] EFA is 50% or more of the [at least one EFA] formulation.

33. (Currently amended) The formulation of claim 16, wherein the [formulation comprises] EFA is 90% or more of the [at least one EFA] formulation.

24 34. (Currently amended) The formulation of claim 16, wherein the [formulation comprises] EFA is 95% or more of the [at least one EFA] formulation.

35. (Original) The formulation of claim 16, wherein vitamin B12 is the only homocysteine-lowering agent.

36. (Original) The formulation of claim 35, wherein vitamin B12 is in the form of hydroxocobalamin.

25 37. (Currently amended) The formulation of claim 16, wherein folic acid [or the related compound] is the only homocysteine-lowering agent.

38. (Original) The formulation of claim 16, wherein the formulation is in a form suitable for oral administration.

39. (Original) The formulation of claim 16, wherein the antioxidant is selected from the group consisting of: natural, synthetic or semi-synthetic vitamin E; natural, synthetic or semi-synthetic coenzyme Q; natural, synthetic or semi-synthetic alpha-lipoic acid; and natural, synthetic or semi-synthetic vitamin C.

/ 40. (Cancelled)

/ 41. (Cancelled)

42. (Original) The formulation of claim 16, wherein the EFA is in the form of a natural oil.

43. (Original) The formulation of claim 42, wherein the natural oil is fish oil.

44. (New) A method of treating a subject in need of homocysteine-lowering therapy which comprises administering to the subject the formulation of claim 16.

45. (New) A method of treating a subject in need of homocysteine-lowering therapy which comprises administering to the subject the formulation of claim 24.

46. (New) The method of claim 44, wherein the subject suffers from one or more of the following conditions:

(a) a cardiovascular disorder; a cerebrovascular disorder; atherosclerosis; heart disease; cerebrovascular disease; stroke; peripheral vascular disease; thrombosis;

(b) diabetes; pre-diabetes (syndrome X); macrovascular complications of diabetes; microvascular complications of diabetes; cardiovascular disease, retinopathy; nephropathy; neuropathy;

(c) a psychiatric disorder; schizophrenia; a schizotypal disorder; a schizophreni form disorder; bipolar disorder (mania, or manic depression); depression; a panic disorder; an anxiety disorder; a sleep disorder; a social phobia;

(d) a neurological disorder; a neurodegenerative disorder; Alzheimer's disease; dementia; Parkinson's disease; multiple sclerosis; Huntington's disease; chronic pain;

(e) a kidney disorder;

(f) an inflammatory or an immunological disorder of the gastrointestinal tract, the respiratory system, the skin and mucous membranes, or the joints or other tissues;

(g) an eye or hearing disorder; age-related macular degeneration; age-related deafness; tinnitus.

(h) obesity; or

(i) cancer.

47. (New) The method of claim 45, wherein the subject suffers from one or more of the following conditions:

(a) a cardiovascular disorder; a cerebrovascular disorder; atherosclerosis; heart disease; cerebrovascular disease; stroke; peripheral vascular disease; thrombosis;

(b) diabetes; pre-diabetes (syndrome X); macrovascular complications of diabetes; microvascular complications of diabetes; cardiovascular disease, retinopathy; nephropathy; neuropathy;

(c) a psychiatric disorder; schizophrenia; a schizotypal disorder; a schizophreni form disorder; bipolar disorder (mania, or manic depression); depression; a panic disorder; an anxiety disorder; a sleep disorder; a social phobia;

(d) a neurological disorder; a neurodegenerative disorder; Alzheimer's disease; dementia; Parkinson's disease; multiple sclerosis; Huntington's disease; chronic pain;

(e) a kidney disorder;

(f) an inflammatory or an immunological disorder of the gastrointestinal tract, the respiratory system, the skin and mucous membranes, or the joints or other tissues;

(g) an eye or hearing disorder; age-related macular degeneration; age-related deafness; tinnitus.

(h) obesity; or

(i) cancer.